REMARKS

Claim Rejections Under 35 USC 112, second paragraph

The Office Action rejects claims 9 and 24 for reciting "soluble constituents." This term was deleted from the rejected claims as it was superfluous.

Claim Rejections Under 35 USC 112, first paragraph

The Office Action alleges lack of written description for a variety of reasons.

One of the lines of reasoning includes the allegations that the disclosure of group 13 grass allergens in the art does not appear to have occurred prior to the filing of applicant's instant invention, that structural information on the group 13 allergens is not provided, that determination of whether a compound is an allergen is not based upon intrinsic properties, e.g., that there does not appear to be any correlation between structure of a group 13 allergen and its role in human allergy.

The second line of reasoning includes the allegation that it is known that many previously identified allergens are not present in all Gramineae pollens.

Enclosed are two documents, i.e., *Petersen et al.* "Group 13 grass allergens: Structural variability between different grass species and analysis of proteolytic stability", J Allergy Clin Immunol, Volume 107, Number 5, pages 856-862 and *Suck et al.*, "Complementary DNA cloning and expression of a newly recognized high molecular mass allergen Phl p 13 from timothy grass pollen (*Phleum pretense*)", Clinical and Experimental Allergy, 2000, Volume 30, pages 324-332. (Both of these articles include the three inventors of this application as co-authors.) *Petersen et al.* was submitted on August 23, 1999, revised on November 3, 1999, and accepted on November 8, 1999, and published in 2000. *Suck et al.*, was received for publication on August 7, 2000, revised on December 21, 2000, and accepted for publication on January 8, 2001, and published in May 2001. Both of these references, cite to various previous publications prior to the filing date of the present application, i.e., August 18, 2000 (PCT filing date), with a priority date of August 24, 1999, and refute the allegations outlined above, including the allegations regarding the state of the art about group 13 allergens.

For example, the designation "Phl p 13" was not determined, designated or invented by applicants. Rather it was applied for and appointed in 1999 by the International Union of Immunological Sciences (WHO-IUIS, Allergen Nomenclature Subcommittee) prior to the filing of the priority date of the present application. See *Petersen et al.*, page 856, right

column, 3rd paragraph. The name stands for Major Allergen 13 from Phleum pretense. In order for the WHO-IUIS to determine the allergen name, submission of physical characteristics of the allergen, including a proof that the protein is an allergen at all were required. *Petersen et al.* additionally specifically teaches in said 3rd paragraph that this allergen was recognized by more than 50% of the individuals with grass pollen allergy. Therefore, there is no doubt that the inventors of the instant patent application (all of whom are also authors of *Petersen et al.* and also authors of the two references cited in said 3rd paragraph, of *Petersen et al.*) and also others in the art were in the possession of these data and information or could have access to it at the filing date, and also even at the priority date, of the present application.

Additionally, prior to the filing of the present application, the Phl p 13 sequence was disclosed in patent application U.S. Serial No. 09/959,340 (PCT application filed on April 12, 2000, with a priority of April 23, 1999). In the patent specification of US 09/959,340 the name Phl p 13 was not used however.

Suck et al. deals with the cloning, sequencing, expression and immunological characterization of Phl p 13, whereas *Petersen et al.* discloses the purification method according to the invention applied to Phl p 13 and group 13 allergens from other grass species.

Suck et al., demonstrates that the protein is in fact an allergen (page 330, left column, 1st paragraph and Figures pointed to therein). Additionally, by sequence comparison it is concluded that the protein is a polygalacturonase (Abstract, Conclusion) which enzyme is known as a human allergen also from other grasses (*Petersen et al.*, page 861, paragraph bridging the columns on said page).

The Office Action correctly points out that the examples of the specification relates only to *Phleum pretense*. However, such is not an adequate basis for the rejection.

It is not necessary that every permutation within a generally operable invention be exemplified in order for an inventor to obtain a generic claim, provided that the effect is sufficiently demonstrated to characterize a generic invention. See *In re Angstadt*, 537 F.2d 498, 190 USPQ 214 (CCPA 1976)..

In *Angstadt*, the Court noted that "many chemical processes, and catalytic processes particularly, are unpredictable" and that applicants' specification further demonstrated that the particular process claimed itself is "unpredictable." Yet, the Court held that "we cannot agree with the board that appellants' disclosure is not sufficient to enable one of ordinary skill in

the art to practice the invention without undue experimentation."

The Court phrased the question in point as follows:

> The question, then, is whether in an unpredictable art, section 112 requires disclosure of a test with every species covered by a claim. To require such a complete disclosure would apparently necessitate a patent application or applications with "thousands" of examples or the disclosure of "thousands" of catalysts along with information as to whether each exhibits catalytic behavior resulting in the production of hydroperoxides. More importantly, *such a requirement would force an inventor seeking adequate patent protection to carry out a prohibitive number of actual experiments*. This **would tend to discourage inventors from filing patent applications in an unpredictable area since the patent claims would have to be limited to those embodiments which are expressly disclosed**.
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> Appellants have broadly disclosed a class of catalyst complexes whose use they deem to be part of their invention. But for this disclosure the public may have been deprived of the knowledge of appellants' process. In this art the performance of trial runs using different catalysts is "reasonable," even if the end result is uncertain, and we see no reason on this record why appellants should not be able to claim as their invention the broad range of processes which they have discovered. (Emphasis added.)

The Court in *Angstadt* recognized that if the USPTO would be able to force applicants to restrict the claims to exemplified matter only in an unpredictable area where certain embodiments within the claims do not achieve the desired results, such would discourage inventors from filing applications.

Thus, as in *Angstadt*, the rejection of the present claims as allegedly not complying with the requirements of section 112, first paragraph, and forcing applicants to restrict the claims to exemplified matter only, are not warranted. One or ordinary skill in the art can perform trial runs using different grasses by performing the claimed purification process, even if the end result, e.g., whether a group 13 allergen will be purified, may have some uncertainty associated with it.

While the rejection in *Angstadt* was an enablement rejection, i.e., sufficiency of disclosure, the Federal Circuit cited it in *Capon v. Eshhar*, 418 F.3d at 1357, 76 USPQ2d 1078 (CA FC 2005), in the context of a lack of written description rejection.

In *Capon* the invention was directed to novel genetic material described in terms of the functional characteristics of the protein it encodes. The specification did not provide a description of the full scope of the chimeric DNA or encoded proteins, but provided procedures for identifying and obtaining the desired immune-related DNA segments and linking them into the desired chimeric genes. A written description rejection followed. The Federal Circuit decided that:

> The descriptive text needed to meet these [written description] requirements varies with the nature and scope of the invention at issue, and with the scientific and technologic knowledge already in existence.
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> The **Board erred in holding that the specifications do not meet the written description requirement because they do not reiterate the structure or formula or chemical name** for the nucleotide sequences of the claimed chimeric genes. (Emphasis added.)

Thus, the requirement that applicants provide structural information, etc., for the group 13 allergens is not warranted in the present case where it is demonstrated that prior art can provide such information to those or ordinary skill in the art.

As it appears in the present case too, claim scope was also a concern of the USPTO in *Capon*.

> The PTO points out that for biochemical processes relating to gene modification, protein expression, and immune response, **success is not assured**. **However, generic inventions are not thereby invalid**. Precedent distinguishes among generic inventions that are adequately supported, those that are merely a "wish" or "plan."
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> "[I]t must be borne in mind that, while it is necessary that an applicant for a patent give to the public a complete and adequate disclosure in return for the patent grant, **the certainty required of the disclosure is not greater than that which is reasonable**, having due regard to the subject matter involved."
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> [T]he Board erred in ruling that §112 imposes a per se rule requiring recitation in the specification of the nucleotide sequence of claimed DNA, when that sequence is already known in the field. (Emphasis added.)

Falkner v. Inglis, 448 F.3d 1357, 79 USPQ2d 1001 (Fed. Cir. 2006), further

confirmed the holding in *Capon*. In *Falkner* the invention related to "a way of making vaccines safer by deleting or inactivating an *essential,* rather than an inessential, gene from the viral vector's genome." The approach was taught to be applicable to many different kinds of vector viruses. Detailed description of only the herpes virus was present in the specification, with pox virus being mentioned. The specification did not identify any *essential* genes in pox virus or describe the inactivation of such *essential* genes. Moreover, the specification specifically admitted that vaccines were not produced with pox virus. The claimed invention was however directed to the making of a vaccine with a pox virus. A written description rejection followed. The Federal Circuit decided that:

> [W]e hold, in accordance with our prior case law, that (1) examples are not necessary to support the adequacy of a written description (2) the written description standard may be met (as it is here) even where actual reduction to practice of an invention is absent; and (3) **there is no per se rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure.**
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> ...
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> [W]e hold that where, as in this case, accessible literature sources clearly provided, as of the relevant date, genes and their nucleotide sequences (here "essential genes"), **satisfaction of the written description requirement does not require either the recitation or incorporation by reference (where permitted) of such genes and sequences**. (Emphasis added.)

Although not directly relevant to the rejection here, in *Petersen et al.*, it is shown that group 13 allergens from 10 different grass species can be purified by the method according to the invention (page 857, right column, 2nd chapter; page 858, Figure 2). Moreover, the proteins in *Petersen et al.* were characterized as allergens and found to be cross-reactive (page 858, chapter "Identification..."). The purified allergens include species other than Pooideae, e.g., *C. dactylon, F. pratensis, Z. mays*. (This can be determined from the Table 1 of the reference by *Esch*, which is cited by the Office Action on page 3.) See page 858 of *Petersen et al.*, paragraph spanning the columns of said page. From the cross-reactivity, their sequence homologies as polygalacturonases, one of ordinary skill in the art would conclude that the group 13 allergens are highly similar in their properties across the Gramineae species. As such, one or ordinary skill in the art would expect that the claimed purification method can be

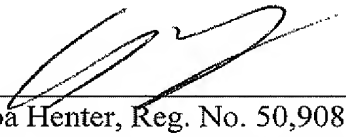
applied to any Gramineae group 13 allergen.

Additionally, whether other allergens, e.g., allergens of groups 5 and 6, are alleged to be found in a subset for the members of Gramineae is irrelevant. Purification of allergens of groups 5 and 6 is not an objective of the claims herein. Such an allegation suggests nothing about what one of ordinary skill in the art would know or expect from a group 13 allergen.

For all the foregoing reasons, reconsideration of the rejection is respectfully requested.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



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